

JAN 21 2004

K034019
Poly Per-Q-Cath PICC
Special 510(k)

Section 6

510(k) Summary 6 Fr DL Poly Per-Q-Cath® PICC Catheters

510(k) Summary of Safety and Effectiveness Information 21 CFR 807.92

6.1 Submitter Information:

Submitter Name: Bard Access Systems, Inc.
[Subsidiary of C. R. Bard, Inc.]
Address: 5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
Telephone Number: (801) 595-0700, Ext. 4903
Fax Number: (801) 595 5425
Contact Person: Michaela Rivkovich
Date of Preparation: December 23, 2003

6.2 Device Name:

Device Name: Poly Per-Q-Cath PICC (Peripherally Inserted Central Catheter)
Trade Name: Poly Per-Q-Cath PICC Catheter
Common/Usual Name: Poly Per-Q-Cath PICC
Classification Name: Long Term Intravascular Catheter (80LJS)

6.3 Predicate Device:

Device Name: Poly Per-Q-Cath PICC (Peripherally Inserted Central Catheter)
Trade Name: Poly Per-Q-Cath PICC Catheter
Common/Usual Name: Poly Per-Q-Cath PICC
Classification Name: Long Term Intravascular Catheter (80LJS)
Premarket Notification: K031129, cleared for marketing on May 5, 2003

6.4 Device Description

- The Poly Per-Q-Cath PICC Catheters are open-ended radiopaque polyurethane catheters.
- Catheter sizes are 3, 4, 5 Fr SL and 5, 6 Fr DL with 60 cm usable length.
- The catheter has a reverse taper design.
- The catheter extension legs are polyurethane extrusions. Extension legs are 2.2 in. in length and each leg has a thumb clamp.
- Catheter tubing is marked with depth indicators, with "0" indicated to serve as a reference for the catheter insertion point.
- Catheters are provided sterile in basic, intermediate and RadPICC kit configurations.

6.5 Intended Use

The modified Poly Per-Q-Cath PICC catheter is intended for short- or long-term peripheral access to the central venous system for intravenous therapy and blood sampling.

6.6 Summary of Technological Characteristics in Relation to Predicate Device:

Does the new device have the same indication statement?

Yes.

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Does the new device have the same technological characteristics, e.g. design, material, etc.?

Not in all regards. There are some minor differences between the predicate and the subject devices. However, the basic fundamental scientific technology of the catheters has not changed.

Could the new characteristics affect safety or effectiveness?

Yes. The changes could affect safety and effectiveness of the device.

Do the new characteristics raise new types of safety and effectiveness questions?

No. There are no new issues of safety and effectiveness.

Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. The FDA's *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters*, dated 3/16/95, and relevant ISO Standards were used to determine the appropriate methods for evaluating the modified device's performance.

Biocompatibility requirements of ISO-10993, *Biological Evaluation of Medical Devices Part-1: Evaluation and Testing*, and the FDA-Modified ISO 10993 Test Profile for externally communicating, blood-contacting, long-term devices, were met.

Are performance data available to assess effects of new characteristics?

Yes. Verification testing was performed according to protocols based on the above-referenced guidance document recommendations and standards, as well as in accordance with in-house protocols. The modified device met the acceptance criteria for the tests performed.

Do performance data demonstrate equivalence?

Yes. Performance data demonstrated that the modified Poly Per-Q-Cath PICC is substantially equivalent to the predicate device, and the risks associated with the use of the new device were found acceptable when evaluated by FMEA.

6.7 Conclusion

The modified Poly Per-Q-Cath PICC met predetermined performance acceptance criteria of testing performed and is substantially equivalent to the predicate Poly Per-Q-Cath PICC catheter, cleared under K031129.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 21 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Michael Rivkovich
Senior Regulatory Affairs Specialist
Bard Access System, Incorporated
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K034019

Trade/Device Name: Poly Per-Q-Cath PICC
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted long-term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: December 23, 2003
Received: December 24, 2003

Dear Mr. Rivkovich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph., D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Section 1.2

INDICATION(S) FOR USE STATEMENT*

The Poly Per-Q-Cath PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy and blood sampling. For blood therapy, it is recommended that a 4 French or larger catheter be used.

Signature of 510(k) Submitter:

Michaela Rivkovich

Printed Name of Submitter:

Michaela Rivkovich
Sr. Regulatory Affairs Specialist

Date:

12/22/03

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.

Concurrence of Office of Device Evaluation

510(k) Number

K034019

Division Sign-Off

Office of Device Evaluation

Prescription Use

✓

OR

Over-The-Counter Use

Vivian Hubbard, Interim Branch Chief
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number. K034019

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